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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/161,680 09/28/98 BORNSCHEUER

U 48429

EXAMINER

HM22/0323

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KERR, K	
ART UNIT	PAPER NUMBER

1652

DATE MAILED:

03/23/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/161,680

Applicant(s)

Bornscheuer et al.

Examiner

Kathleen Kerr

Group Art Unit
1652

☒ Responsive to communication(s) filed on 3/2/00

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-9 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-9 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Application Status

1. The amendment filed on March 6, 2000 has been entered deleting claim 3 and amending claims 1, 2, 4, and 6 of the previously pending claims 1-9. Thus, claims 1, 2, and 4-9 are pending in the instant application. Based on the priority documents received in the Office, the date before which art is considered prior art for the instant application is October 2, 1997.

It is noted in Applicants have considered the Office action (Paper No. 7) mailed on November 30, 1999 as a final Office action as stated in their amendment filed on March 6, 2000; this is incorrect as noted in the Office Action Summary (PTO-326) where the "This action is **FINAL**" box is unchecked.

Information Disclosure Statement

2. The Winnacker reference, previously noted as lacking in its citation information, is not considered for the following reasons:
- a. The citation is in correct having the wrong publisher CVH; the correct publisher is VCH.
 - b. The copy of the citation is incomplete containing no reference to the title, author, or publisher making it impossible for the Examiner to determine where, in fact, the citation originated.

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For proper consideration of this reference, the citation on the IDS must be corrected and a more complete copy of the reference must be provided.

3. As previously noted, the Harpes reference has not been considered in the absence of a copy of the reference.

Objections to the Claims

4. Claim 5 is objected to because of the following informalities:
 - a. Upon amendment, the language of claim 5 is improper. Applicants are requested to insert "a" before hydrolase in line 2 and to delete "is used as enzyme" also in line 2.

Appropriate correction is required.

Previous Objections to the Specification

5. The specification is no longer objected to by the Examiner having been corrected according to the Examiner's objections to the specification in the previous Office action (Paper No. 7) by amendment.

Previous Objections to the Claims

6. The Examiner's previous objection to claim 3 for a failure to further limit is moot and, thus, withdrawn by virtue of applicants' cancellation of claim 3.

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Response to Arguments

7. The rejection of claims 1 and 2 under 35 U.S.C. 112, second paragraph, is withdrawn. The amendments to claims 1 and 2 have clarified the claim language such that claims 1 and 2 now distinctly point out that which applicants are claiming.

8. The rejection of claims 6 and 7 under 35 U.S.C. 112, second paragraph, is held by the Examiner. Applicants' arguments have been fully considered, but they are not persuasive as discussed below.

The Markush group in claim 6 is described as hydrolases, and as such, all the members of the Markush group must be classified as hydrolases. Nitrilases can be classified as both hydrolases (E.C. 3.) and lyases (E.C. 4.), thus causing ambiguity and a lack of clarity in claim 6. Peroxidases are not hydrolases but are oxidoreductases (E.C. 1.). While it is noted that applicants have defined all the members of the Markush group in the specification and that applicants may be their own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See M.P.E.P. 7.34.02 and *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The Enzyme Commission (EC) has set forth the classification of enzymes which is accepted by skilled artisans and which is in contrast to applicants' classification. Therefore, the Markush group of claim 6 is, in fact, improper, rendering claim 6 indefinite.

The Markush group in claim 7 contains a member which is a subset of another member; a phytase is classified as an esterase. By including a redundant member in a Markush group,

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applicants have implied an alternate, non-redundant meaning, to the term "phytase". Therefore, the Markush group of claim 7 is, in fact, improper, rendering claim 7 unclear.

9. The rejection of claims 1-2 and 4-8 under 35 U.S.C. 102(b) as being anticipated by Greener et al. is held by the Examiner. Applicants' arguments that the Examiner has not met the burden of making a *prima facie* case have been fully considered, but they are not persuasive as discussed below.

While it is true that Greener et al. do not use the term "substrate specificity" and applicants' have claimed a method of altering substrate specificity, the method steps found in instant claims 1, 2, and 4-8 are all employed by Greener et al., and, thus, Greener et al. are inherently practicing applicants' method of altering substrate specificity. Furthermore, the Examiner did not misquote Greener et al. since the text in quotation in the Examiner's Office action (Paper No. 7) is verbatim from the reference with the exception of the terms in parentheses inserted for clarity. Applicants seem to be arguing that the Examiner's agreement with the conclusions and/or presumptions of Greener et al. is not valid while the Examiner specifically noted in the previous Office action that the conclusion of Greener et al. were considered valid.

Specifically, Greener et al. practice the method steps of claims 1, 2 and 4-8, including step 1e) "selecting the microorganisms which show an alteration in the substrate specificity", when they assay for increased (or decreased) enzymatic activity (see Greener et al., page 383, #8)

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because any change in enzyme activity is indicative of an alteration in substrate specificity as noted in the previous Office action (Paper No. 7).

10. The rejection of claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over Greener et al. in view of Wilks et al. is withdrawn by the Examiner.

11. The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Greener et al. in view of Wilks et al. is held by the Examiner. Applicants' arguments have been fully considered, but they are not persuasive as discussed below.

In response to applicants' argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In the instant case, the use of Greener et al. is held as described in section 9. Wilks et al. teach a complex mutagenesis method which the Examiner noted as "irrelevant" in the previous Office action (Paper No. 7). The addition of the Wilks et al. reference to Greener et al. is to cite the knowledge in the art concerning the ability to mutate enzymes, whether randomly as taught by

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Greener et al. or rationally as taught by Wilks et al., to produce enzymes with new, stereoselective substrate specificities as claimed in claim 9. Although claim 9 currently reads on any change in substrate specificity because of the recited selectivities of the Markush group of claim 9 (these "selectivities" are, in fact, not selective at all over claim 1), this rejection is directly specifically to the alteration of stereoselective enzymatic activities. The motivation for such a combination is evident in the introduction of Wilks et al. which equates "random mutagenesis and screening" with "rational design and construction" (see page 561, first paragraph). It is clear that if Wilks et al. can produce enzymes with new, stereoselective substrate specificities via rational, directed mutagenesis, then the random methods taught by Greener et al. would also produce such new enzymes when practiced in high enough quantity.

In response to applicants' argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

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Conclusion

Applicant's amendment necessitated the new objection (see section 4) presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.



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KMK

March 20, 2000